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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,217	12/09/2005	Jeffrey H. Yanof	PHUS030182US	4972

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EXAMINER	
EVOY, NICHOLAS LANE	
ART UNIT	PAPER NUMBER
3768	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/560,217	YANOF ET AL.	
	Examiner	Art Unit	
	NICHOLAS L. EVOY	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 September 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☒ Claim(s) *1,10 and 19* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 September 2009* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/9/2005 and 1/10/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claims 1, 10 and 19 objected to because of the following informalities: The language of the claim and the elements claimed are presented in an indirect fashion that could create confusion. In the claim language, the "holding area" is operative to translate the medical device along a selected linear path, however as disclosed in the specification the holding area is for holding the system and a linear slide joint actually provides this aspect. Appropriate changes are required.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-8, 10-17 and 19 rejected under 35 U.S.C. 103(a) as being unpatentable over Kwoh et al, US Patent Number 5,078,140 in view of McIntyre, IV, US patent Number 6,468,226 B1.

3. In re claims 1, 10 and 19, Kwoh discloses a system, method or apparatus for inserting a medical device into a patient including an imaging device scanning the patient to generate a volumetric image data set of the patient, a human readable device for displaying an image of the patient derived from the volumetric image data set,

means for selecting a virtual trajectory defining a path for inserting the medical device into the patient, robotic means on the imaging device and movable into selected positions relative to the imaging device, and a guide apparatus to direct movement of the medical device relative to the patient disposed on the robotic means, the guide apparatus comprising: a connector portion coupling the guide apparatus with the associated imaging device at a distal end of the robotic means (from column 2, line 62 to column 3, line 9); a main body portion supported relative to the associated imaging device by the connector portion (see Figs. 1, 4 and 5); a gripping area formed at a first end of the main body portion, the gripping area adapting the guide apparatus for manual gripping by an associated operator (i.e. when the disclosed robotic system is in a mode for manual surgical operation; see column 6, line 57 to column 7, line 2); and, a holding area formed at a second end of the main body portion, the holding area holding the medical device in an orientation suitable for motion relative to the patient along a selected linear path, the holding area being operative to translate the medical device along the selected linear path in response to manual force applied by the associated human operator at the gripping area (see from column 5, line 17 to column 10, line 4).

4. Kwoh does not disclose that the medical device is translated along said linear path in response to manual force applied by the associated human operator at said gripping area during insertion of the medical device. McIntire teaches a remote tissue biopsy apparatus that inserts and slides a biopsy needle along a linear trajectory in response to a manual force applied by a human operator at a knob (Column 8, Lines 53-65, Column 10, Lines 23-40 and Figures 1 and 2). It would have been obvious to one

of ordinary skill in the art at the time the invention was made to combine the teachings of Kwoh and McIntyre because linear insertion of the device during the medical procedure increases accuracy of the procedure in cases where the insertion site is not visible to the technician (McIntyre: Column 1, Lines 58 - Column 2, Lines 11).

5. In re claims 2 and 11, Kwoh discloses that the imaging device is a CT scanner, an MRI scanner, a CCT scanner, a fluoroscope, a SPECT scanner, a PET scanner, or a combination of the foregoing (i.e. for specific use in CT, MRI, ultrasound or PET imaging; see column 2, lines 61-68).

6. In re claims 3 and 12, Kwoh discloses that the medical device is an ablation probe or a biopsy needle (i.e. using the system for a needle biopsy surgery; see column 9, lines 6-12).

7. In re claims 4 and 13, Kwoh discloses that the means for selecting the virtual trajectory includes means for selecting a virtual target point in the image of the patient by identifying a first coordinate in the image of the patient, and means for identifying a virtual path extending from the selected virtual target point and out from the body of the patient (i.e. utilizing stereotactic software for use with a CT scanner and interfacing with a robotic arm for surgeon interaction; see column 6, line 5-23).

8. In re claims 5 and 14, Kwoh discloses that the robotic means is adapted to move the guide apparatus into a position whereat the medical device is in an orientation suitable for motion relative to the patient along the selected linear path coincident with the virtual path extending from the virtual target point and out from the body of the

patient (i.e. a system that moves linearly in line with a predetermined surgical path; see column 5, line 23 to column 6, line 23).

9. In re claims 6 and 15, McIntire teaches a remote tissue biopsy apparatus that inserts and slides a biopsy needle along a linear trajectory in response to a manual force applied by a human operator at a knob (Column 8, Lines 53-65, Column 10, Lines 23-40 and Figures 1 and 2).

10. In re claims 7 and 16, Kwoh discloses that the position feedback device provided on the connector portion of the guide apparatus for providing a feedback signal indicating a position of the guide apparatus relative to the patient (i.e. encoders present that provide position and velocity feedback; see column 4, lines 1-6) and means for displaying an image of the medical device as it is physically moved relative to the patient based upon feedback signal, together with the image of the patient and the virtual path (i.e. the N-shaped locators that provide spatial position references that show up in cross-sectional images obtained by operating the CT scanner; see column 6, lines 24-40).

11. In re claims 8 and 17, Kwoh discloses that the holding area is formed of an x-ray transmissive material (i.e. the N-shaped locators that provide spatial position references that show up in cross-sectional images obtained by operating the CT scanner; see column 6, lines 24-40).

12. Claims 9, 18 and 20 rejected under 35 U.S.C. 103(a) as being unpatentable over Kwoh et al, US Patent Number 5,078,140 in view of McIntyre, IV, US Patent Number

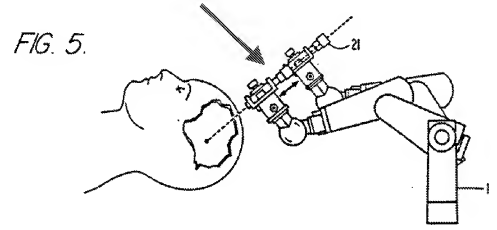
6,468,226 B1 as applied to claims 1-8, 10-17 and 19 above, and further in view of Johnson, US Patent Number 3,893,813.

13. Regarding claims 9, 18 and 20, Kwoh and McIntyre teach an imaging device and surgical method and apparatus as referenced above. Kwoh and McIntyre do not disclose that the holding area includes a set of tweezers-like arm portions adapted to grip the medical device in a V-shaped groove formed by the arm portions. Johnson teaches using a clamp with tweezers-like arm portions for use with chemical equipment in a laboratory setting, such as with pipettes and other precision instruments (see from column 1, line 64 to column 2, line 33 and Figures 1-3 and 6). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the system, method or apparatus of Kwoh and McIntyre with the feature of a set of tweezers-like arm portions of the medical device holding mechanism as taught by Johnson as Kwoh and McIntyre and Johnson are directed to the system, method or apparatus for inserting a medical device into a patient, so as to give a sure way for mounting medical devices to the surgical system while still preserving the accuracy of the device and the sturdiness of the mount.

Response to Arguments

14. Regarding Applicants arguments that the reference of Kwoh does not disclose a guide apparatus having a holding area operative "to translate a medical device along a linear path in response to manual force applied by a human operator manually gripping a gripping area of the guide apparatus during the insertion of the medical device". Kwoh

discloses a robotic arm for inserting a medical device along a linear path in response to manual force applied by a human operator manually gripping a gripping area of the guide apparatus (Kwoh: Column 6, Lines 57-67). With regard to applicant's argument, applicant is directed to Kwoh, Figure 5:



15. Kwoh specifically shows in Figure 5 that the guide apparatus is operative to translate a medical device along a linear path. Additionally, Kwoh discloses that the robotic arm can be manually manipulated in "free" mode such that the arm is capable of being used for surgical insertion purposes (Kwoh: Column 6, Line 67 - Column 7, Line 2).

16. With regard to applicants argument that there is no provision in Kwoh to constrain the "free" movement of the probe to a linear insertion path: Applicant's claims recite "the holding area holding the medical device in an orientation suitable for motion relative to said patient along a selected linear path, the holding area being operative to translate the medical device along said selected linear path in response to manual force

applied by the human operator...". Kwoh meets these claim limitations, as Applicant's claims do not recite constraining movement exclusively to a linear path, and the invention of Kwoh is capable of moving in a linear path, as shown in above referenced Figure 5.

17. With regard to Applicant's amendment of independent claims 1, 10 and 19: Applicant has added the claim limitation of "...during insertion of the medical device" which was not previously present in the claim language. As such, by combing the reference of Kwoh with the reference of McIntyre IV, it would have been obvious to one of ordinary skill in the art at the time the invention was made to produce the claimed invention (See rejections above under U.S.C. § 103)

18. Applicant's arguments with respect to claims 1-20 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

19. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Yanof et al, US Patent Number 5,957,933. Magnusson et al, US Patent Number 5,280,427.

20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NICHOLAS L. EVOY whose telephone number is (571)270-1388. The examiner can normally be reached on M-F 7:30-5:00, Alternating Fridays Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NLE 12/31/09

/Long V Le/

Supervisory Patent Examiner, Art Unit 3768